(b) *Classification.* Class II (performance standards).

**§ 870.1435 Single-function, preprogrammed diagnostic computer.**

(a) *Identification.* A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

(b) *Classification.* Class II (performance standards).

**§ 870.1450 Densitometer.**

(a) *Identification.* A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

(b) *Classification.* Class II (performance standards).

**§ 870.1650 Angiographic injector and syringe.**

(a) *Identification.* An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

(b) *Classification.* Class II (performance standards).

**§ 870.1660 Indicator injector.**

(a) *Identification.* An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjuction with a densitometer or thermodilution device to determine cardiac output.

(b) *Classification.* Class II (performance standards).

**§ 870.1670 Syringe actuator for an injector.**

(a) *Identification.* A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

(b) *Classification.* Class II (performance standards).

**§ 870.1750 External programmable pacemaker pulse generator.**

(a) *Identification.* An external programmable pacemaker pulse generators is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

(b) *Classification.* Class II (performance standards).

**§ 870.1800 Withdrawal-infusion pump.**

(a) *Identification.* A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.

(b) *Classification.* Class II (performance standards).

**§ 870.1875 Stethoscope.**

(a) *Manual stethoscope*—(1) *Identification.* A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) *Electronic stethoscope*—(1) *Identification.* An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification.* Class II (performance standards).

[45 FR 7907-7971, Feb. 5, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38796, July 25, 2001]

**§ 870.1915 Thermodilution probe.**

(a) *Identification.* A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

(b) *Classification.* Class II (performance standards).